P2 1154048

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

June 14, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: *PCT/US03/12027*
FILING DATE: *April 18, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/01092*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

H. L. Jackson

H. L. JACKSON
Certifying Officer

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

TRANSMITTAL LETTER TO THE UNITED STATES RECEIVING OFFICE

Date	18 April 2003
International Application No.	PCT/US 03/12027
Attorney Docket No.	7153.020

I. Certification under 37 CFR 1.10 (if applicable)

EV 216213321 US	18 April 2003
Express Mail mailing number	Date of Deposit

I hereby certify that the application/correspondence attached hereto is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Assistant Commissioner for Patents, Washington, D.C. 20231.

Kathleen C Tennant	Kathleen C. Tennant
Signature of person mailing correspondence	Typed or printed name of person mailing correspondence

II. ☑ **New International Application**

TITLE	Supplemental Ozone Treatment Methods for Difficult Cleaning and Sterilizing Applications	Earliest priority date (Day/Month/Year)

SCREENING DISCLOSURE INFORMATION: In order to assist in screening the accompanying international application for purposes of determining whether a license for foreign tranmittal should and could be granted and for other purposes, the following information is supplied. (Note: check as many boxes as apply):

A. ☐ The invention disclosed was **not** made in the United States.

B. ☑ There is no prior U.S. application relating to this invention.

C. ☐ The following prior U.S. application(s) contain subject matter which is related to the invention disclosed in the attached international application. (*NOTE: priority to these applications may or may not be claimed on form PCT/RO/101 (Request) and this listing does not constitute a claim for priority.)*

application no.		filed on	
application no.		filed on	

D. ☐ The present international application contains additional subject matter not found in the prior U.S. application(s) identified in paragraph C. above. The additional subject matter is found on pages ____ and ☐ **DOES NOT ALTER** ☐ **MIGHT BE CONSIDERED TO ALTER** the general nature of the invention in a manner which would require the U.S. application to have been made available for inspection by the appropriate defense agencies under 35 U.S.C. 181 and 37 CFR 5.1. See 37 CFR 5.15

III. ☐ **A Response to an Invitation from the RO/US.** The following document(s) is(are) enclosed:

A. ☐ A Request for An Extension of Time to File a Response

B. ☐ A Power of Attorney (General or Regular)

C. ☐ Replacement pages:

pages		of the request (PCT/RO/101)	pages		of the figures
pages		of the description	pages		of the abstract
pages		of the claims			

D. ☐ Submission of Priority Documents

Priority document		Priority document	

E. ☐ Fees as specified on attached Fee Calculation sheet form PCT/RO/101 annex

IV. ☐ **A Request for Rectification under PCT 91** ☐ **A Petition** ☐ **A Sequence Listing Diskette**

V. ☒ **Other** (please specify):

1. Assignment and Recordation Cover Sheet
2. $40 Check for recordation fee

The person signing this form is the:

☐ Applicant	Gavin J. Milczarek-Desai
☑ Attorney/Agent (Reg. No.) 45,801	Typed name of signer
☐ Common Representative	Signature

PTO-1382 (Rev. 08-1997) U.S. Department of Commerce: Patent and Trademark Office

COPY

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

PCT/US 03/12027
International Application No.

(18.04.03) 18 APR 2003
International Filing Date

PCT INTERNATIONAL APPLICATION RO/US
Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 7153.020

Box No. I TITLE OF INVENTION

Supplemental Ozone Treatment Methods for Difficult Cleaning and Sterilizing Applications

Box No. II APPLICANT ☐ This person is also inventor

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

LANGFORD IC SYSTEMS, INC.
310 S. Williams Boulevard, Suite 270
Tucson, Arizona 85711
United States of America

Telephone No. 520-745-6201
Facsimile No. 520-745-6286
Teleprinter No.
Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

LANGFORD, Terrence R.
4049 Quiet Moon Drive
Tucson, Arizona 85718
United States of America

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

MILCZAREK-DESAI, Gavin J.
Durando Birdwell & Janke, PLC
2929 E. Broadway Boulevard
Tucson, Arizona 85716
United States of America

Telephone No. 520-881-9442
Facsimile No. 520-881-9448
Teleprinter No.
Agent's registration No. with the Office 45,801

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. V DESIGNATION OF STATES *Mark the applicable check-boxes below; at least one must be marked.*

The following designations are hereby made under Rule 4.9(a):

Regional Patent

☒ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **MZ** Mozambique, **SD** Sudan, **SL** Sierra Leone, **SZ** Swaziland, **TZ** United Republic of Tanzania, **UG** Uganda, **ZM** Zambia, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

☒ **EA** **Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakhstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **BG** Bulgaria, **CH & LI** Switzerland and Liechtenstein, **CY** Cyprus, **CZ** Czech Republic, **DE** Germany, **DK** Denmark, **EE** Estonia, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, **SI** Slovenia, **SK** Slovakia, **TR** Turkey, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ **OA** **OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **GQ** Equatorial Guinea, **GW** Guinea-Bissau, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒ **AE** United Arab Emirates	☒ **GM** Gambia	☒ **NZ** New Zealand
☒ **AG** Antigua and Barbuda	☒ **HR** Croatia	☒ **OM** Oman
☒ **AL** Albania	☒ **HU** Hungary	☒ **PH** Philippines
☒ **AM** Armenia	☒ **ID** Indonesia	☒ **PL** Poland
☒ **AT** Austria	☒ **IL** Israel	☒ **PT** Portugal
☒ **AU** Australia	☒ **IN** India	☒ **RO** Romania
☒ **AZ** Azerbaijan	☒ **IS** Iceland	☒ **RU** Russian Federation
☒ **BA** Bosnia and Herzegovina	☒ **JP** Japan	
☒ **BB** Barbados	☒ **KE** Kenya	☒ **SC** Seychelles
☒ **BG** Bulgaria	☒ **KG** Kyrgyzstan	☒ **SD** Sudan
☒ **BR** Brazil	☒ **KP** Democratic People's Republic of Korea	☒ **SE** Sweden
☒ **BY** Belarus		☒ **SG** Singapore
☒ **BZ** Belize	☒ **KR** Republic of Korea	☒ **SK** Slovakia
☒ **CA** Canada	☒ **KZ** Kazakhstan	☒ **SL** Sierra Leone
☒ **CH & LI** Switzerland and Liechtenstein	☒ **LC** Saint Lucia	☒ **TJ** Tajikistan
☒ **CN** China	☒ **LK** Sri Lanka	☒ **TM** Turkmenistan
☒ **CO** Colombia	☒ **LR** Liberia	☒ **TN** Tunisia
☒ **CR** Costa Rica	☒ **LS** Lesotho	☒ **TR** Turkey
☒ **CU** Cuba	☒ **LT** Lithuania	☒ **TT** Trinidad and Tobago
☒ **CZ** Czech Republic	☒ **LU** Luxembourg	
☒ **DE** Germany	☒ **LV** Latvia	☒ **TZ** United Republic of Tanzania
☒ **DK** Denmark	☒ **MA** Morocco	☒ **UA** Ukraine
☒ **DM** Dominica	☒ **MD** Republic of Moldova	☒ **UG** Uganda
☒ **DZ** Algeria		☒ **US** United States of America
☒ **EC** Ecuador	☒ **MG** Madagascar	
☒ **EE** Estonia	☒ **MK** The former Yugoslav Republic of Macedonia	☒ **UZ** Uzbekistan
☒ **ES** Spain		☒ **VC** Saint Vincent and the Grenadines
☒ **FI** Finland	☒ **MN** Mongolia	☒ **VN** Viet Nam
☒ **GB** United Kingdom	☒ **MW** Malawi	☒ **YU** Yugoslavia
☒ **GD** Grenada	☒ **MX** Mexico	☒ **ZA** South Africa
☒ **GE** Georgia	☒ **MZ** Mozambique	☒ **ZM** Zambia
☒ **GH** Ghana	☒ **NO** Norway	☒ **ZW** Zimbabwe

Check-boxes below reserved for designating States which have become party to the PCT after issuance of this sheet:

☒ .NI..Nicaragua.....	☐	☐ .....
☐	☐	☐ .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application *(day/month/year)*	Number of earlier application	Where earlier application is:		
		national application: country or Member of WTO	regional application:* regional Office	international application: receiving Office
item (1)				
item (2)				
item (3)				
item (4)				
item (5)				

☐ Further priority claims are indicated in the Supplemental Box.

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office)* identified above as:

☐ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ item (4) ☐ item (5) ☐ other, see Supplemental Box

** Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)):* ....

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*:

ISA / US

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII DECLARATIONS

The following **declarations** are contained in Boxes Nos. VIII (i) to (v) *(mark the applicable check-boxes below and indicate in the right column the number of each type of declaration)*:

Number of declarations

☐	Box No. VIII (i)	Declaration as to the identity of the inventor :	
☒	Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent :	1
☐	Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application :	
☒	Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America) :	1
☐	Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty :	

Box No. VIII (ii) DECLARATION: ENTITLEMENT TO APPLY FOR AND BE GRANTED A PATENT

The declaration must conform to the standardized wording provided for in Section 212; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (ii). If this Box is not used, this sheet should not be included in the request.

Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51*bis*.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate:

in relation to this international application,

Langford IC Systems, Inc. is entitled to apply for and be granted a patent by virtue of the following:

an assignment from the inventor:

LANGFORD, Terrence R., 4049 Quiet Moon Drive, Tucson, Arizona, 85718, United States of America,

to Langford IC Systems, Inc., dated 18 April 2003.

This declaration is made for the purpose of all designations.

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (ii)".

Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)

The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.

Declaration of inventorship (Rules 4.17(iv) and 51*bis*.1(a)(iv)) for the purposes of the designation of the United States of America:

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/..... (if furnishing declaration pursuant to Rule 26*ter*).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications: .....

.....

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: Terrence R. Langford

Residence: Tucson, Arizona
(city and either US state, if applicable, or country)

Mailing Address: 4049 Quiet Moon Drive
Tucson, Arizona 85718

Citizenship: US

Inventor's Signature: .....
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: 4/11/03
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

Name: .....

Residence: .....
(city and either US state, if applicable, or country)

Mailing Address: .....

.....

Citizenship: .....

Inventor's Signature: .....
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: .....
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application **contains**:

(a) **in paper form**, the following number of sheets :

request (including declaration sheets)	:	~~4~~ 5
description (excluding sequence listings and/or tables related thereto)	:	16
claims	:	4
abstract	:	1
drawings	:	0
Sub-total number of sheets	:	29
sequence listings	:	
tables related thereto	:	
(for both, actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (c) below)		
Total number of sheets	:	~~29~~ 30

(b) ☐ **only in computer readable form** (Section 801(a)(i))
- (i) ☐ sequence listings
- (ii) ☐ tables related thereto

(c) ☐ **also in computer readable form** (Section 801(a)(ii))
- (i) ☐ sequence listings
- (ii) ☐ tables related thereto

Type and number of carriers (diskette, CD-ROM, CD-R or other) on which are contained the
- ☐ sequence listings: . . . . . .
- ☐ tables related thereto: . . . . . .

(additional copies to be indicated under items 9(ii) and/or 10(ii), in right column)

This international application is **accompanied by** the following item(s) *(mark the applicable check-boxes below and indicate in right column the number of each item)*:

		Number of items
1. ☒ fee calculation sheet	:	1
2. ☒ original separate power of attorney	:	1
3. ☐ original general power of attorney	:	
4. ☐ copy of general power of attorney; reference number, if any:	:	
5. ☐ statement explaining lack of signature	:	
6. ☐ priority document(s) identified in Box No. VI as item(s):	:	
7. ☐ translation of international application into *(language)*:	:	
8. ☐ separate indications concerning deposited microorganism or other biological material	:	
9. ☐ sequence listings in computer readable form *(indicate type and number of carriers)*		
(i) ☐ copy submitted for the purposes of international search under Rule 13*ter* only (and not as part of the international application)	:	
(ii) ☐ *(only where check-box (b)(i) or (c)(i) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Rule 13*ter*	:	
(iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listings mentioned in left column	:	
10. ☐ tables in computer readable form related to sequence listings *(indicate type and number of carriers)*		
(i) ☐ copy submitted for the purposes of international search under Section 802(b-*quater*) only (and not as part of the international application)	:	
(ii) ☐ *(only where check-box (b)(ii) or (c)(ii) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Section 802(b-*quater*)	:	
(iii) ☐ together with relevant statement as to the identity of the copy or copies with the tables mentioned in left column	:	
11. ☒ other *(specify)*: Assignment & Recordation Cover Sheet	:	4

Figure of the drawings which should accompany the abstract:

Language of filing of the international application: English

Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Gavin J. Milczarek-Desai, Agent

4-17-03
Date

For receiving Office use only

1. Date of actual receipt of the purported international application: 0T20 Rec'd PCT/PTO 18 APR 2003 (18 APR 03)

2. Drawings:
- ☐ received:
- ☐ not received:

3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:

4. Date of timely receipt of the required corrections under PCT Article 11(2):

5. International Searching Authority (if two or more are competent): ISA / US

6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

This sheet is not part of and does not count as a sheet of the international application.

PCT

FEE CALCULATION SHEET

Annex to the Request

For receiving Office use only

International Application No. PCT/US 03/12027

18.04.03 18 APR 2003

Date stamp of the receiving Office

Applicant's or agent's file reference: 7153.020

Applicant: Langford IC Systems, Inc.

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE	240 [T]	240
2. SEARCH FEE	700 [S]	700

International search to be carried out by US

(If two or more International Searching Authorities are competent to carry out the international search, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

Where items (b) and/or (c) of Box No. IX apply, enter **Sub-total number of sheets** } 29
Where items (b) and (c) of Box No. IX do not apply, enter **Total number of sheets** }

[b1] first 30 sheets	476 [b1]	476
[b2] 0 (number of sheets in excess of 30) x 12 (fee per sheet) =	0 [b2]	0
[b3] additional component (only if sequence listings and/or tables related thereto are filed in computer readable form under Section 801(a)(i), or both in that form and on paper, under Section 801(a)(ii)): 400 x 0 (fee per sheet) =	0 [b3]	0
Add amounts entered at b1, b2 and b3 and enter total at B	476 [B]	476

Designation Fees

The international application contains >5 designations.

5 (number of designation fees payable *(maximum 5)*) x 104 (amount of designation fee) =	520 [D]	520
Add amounts entered at B and D and enter total at I	996 [I]	996

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT *(if applicable)*	[P]	0
5. TOTAL FEES PAYABLE. Add amounts entered at T, S, I and P. and enter total in the TOTAL box	1936 TOTAL	1936

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

☐ authorization to charge deposit account (see below) ☐ postal money order ☐ cash ☐ coupons

☒ cheque ☐ bank draft ☐ revenue stamps ☐ other *(specify)*:

AUTHORIZATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT

(This mode of payment may not be available at all receiving Offices)

Receiving Office: RO/ US

Deposit Account No.: 04-1935

Date: 18 April 2003

Name: Gavin J. Milczarek-Desai

Signature:

☐ Authorization to charge the total fees indicated above.

☒ *(This check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit)* Authorization to charge any deficiency or credit any overpayment in the total fees indicated above.

☐ Authorization to charge the fee for priority document.

PCT

POWER OF ATTORNEY

(for an international application filed under the Patent Cooperation Treaty)

(PCT Rule 90.4)

The undersigned applicant(s) *(Names should be indicated as they appear in the request)*:

Langford IC Systems, Inc.

hereby appoints (appoint) the following person as: [X] agent [ ] common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

MILCZAREK-DESAI, Gavin J.
DURANDO, Antonio R.

Durando Birdwell & Janke, P.L.C.
2929 E. Broadway Blvd.
Tucson, Arizona 85716
United States of America

to represent the undersigned before

[X] all the competent International Authorities
[ ] the International Searching Authority only
[ ] the International Preliminary Examining Authority only

in connection with the international application identified below:

Title of the invention: Supplemental Ozone Treatment Methods for Difficult Cleaning and Sterilizing Applications

Applicant's or agent's file reference: 7153.020

International application number (if already available):

filed with the following Office U.S. Patent and Trademark Office as receiving Office
and to make or receive payments on behalf of the undersigned.

Signature of the applicant(s) *(where there are several applicants, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading the request or this power)*:

Terrence R. Langford, President and Chief Executive Officer

Date:

Form PCT/Model of power of attorney (for a given international application) (July 1992)

SUPPLEMENTAL OZONE TREATMENT METHODS FOR DIFFICULT CLEANING AND STERILIZING APPLICATIONS

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to methods used both to clean items and to ensure that cleaned items are substantially free of biological and/or chemical contaminants and more particularly to methods that are especially useful to ensure the sterility of tubular medical items such as endoscopes.

Description of the Related Art

The cleaning and decontamination of items that come into contact with the bodily substances of people or animals such that they are substantially "substance free" (of, e.g., viruses, bacteria, detergent, sterilant, lipids, etc.) represent an immense and ongoing challenge. This challenge has been underscored by a recent article entitled "Widely used sterilizer under attack" (published in January 21, 2003 edition of the newspaper USA Today). The article describes a fatal outbreak of bacterial infection that was linked to the improper sterilization of hospital bronchoscopes. Despite the hospital's use of one of the most popular sterilizing systems, tests performed by the Centers for Disease Control and Prevention found bacteria on the system's water filters and in its rinse water. This and other infection outbreaks has led to continuing controversy over how best to clean and sterilize used endoscopes.

The contaminants typically found on tubular medical items, such as endoscopes, are especially difficult to remove. In addition to fecal mater, loose cellular debris, blood and blood products, viruses, and bacteria, an endoscope can be coated with various hydrophobic films, such as "biofilm" material. A biofilm typically comprises cells, both dead and alive, cell debris and extracellular polymer substances. Once biofilm is formed by microorganisms (including bacteria, fungi, and protozoans), these microorganisms

can colonize and replicate on the interior surfaces of tubing, forming a protective slime layer known as a "glycocalyx" that is especially difficult to remove.

Merely soaking endoscopes in a sterilant or detergent is unacceptable since numerous pockets exist within the tubing where the sterilant or detergent cannot reach effectively, which leaves areas of contamination within the endoscope. Moreover, with the prevalence of highly contagious diseases such as hepatitis B and Acquired Immune Deficiency Syndrome, reliable sterilization or disposal of all used medical tools seemingly becomes mandatory. Yet, while many medical instruments today are routinely cleaned, disinfected, and reused, experts in the field recently have warned that some of the more difficult to clean and sterilize medical items are putting people at risk.

Indeed, one expert has stated that there are no independent published reports or data anywhere in the medical literature that show liquid chemical sterilants (or any other method/process/agent) can be used to reliably "sterilize" flexible endoscopes or other complex, lumened instruments (See Comments by L. Muscarella (Custom Ultrasonics) on AAMI TIR7:1999, Chemical Sterilants and Sterilization Methods: A Guide to Selection and Use, downloaded from the website myendosite.com).

To the contrary, Kovacs *et al.* reports that a strain of *Pseudomonas aeruginosa* has been repeatedly isolated from tap water used for cleaning and rinsing endoscopes and appears to be responsible for three separate clinical episodes of endoscopic retrograde cholangio-pancreatography (ERCP)-associated cholangitis over an 11-yr period. These authors also conclude that the organism is resistant to a commonly used sterilant because it was recovered from a variety of endoscopes that had undergone stringent reprocessing protocols (see Kovacs BJ, et al. "Efficacy of various disinfectants in killing a resistant strain of *Pseudomonas aeruginosa* by comparing zones of inhibition: Implications for endoscopic equipment reprocessing," *Am J Gastroenterol* 1998;93:2057-9). Thus, there is a genuine need for "overkill" sterilization to help ensure that even chemical-resistant pathogens are effectively eliminated.

In addition to the infection issues, environmental concerns over the content of medical item wash or rinse water effluent have become more pronounced as the detrimental effects (including toxicity) of various cleaning and sterilizing chemicals are now better understood. For example, commonly used liquid chemical sterilants, such as glutaraldehyde and paracetic acid, are known to have adverse health effects or carcinogenic activity. Since most endoscope cleaning and sterilization is accomplished with various detergents in combination with glutaraldehyde or paracetic acid, harmful chemical residue can be left behind both on the item and in the wash or rinse effluent. Therefore, discharge of these chemicals into rivers, lakes, and even sewer systems raises safety issues that have yet to be addressed.

Furthermore, some chemical cleaners or sterilants are so harshly reactive that they can damage the items they are meant to clean or sterilize. Thus, the problems encountered during item (and especially medical item) cleaning and disinfecting primarily involve trying to strike a balance between ensuring as much as possible the complete removal of contaminants and chemicals while, at the same time, not damaging the instrument or the environment.

Even the simple act of rinsing medical items with filtered water after cleaning or sterilization has been called into question. After sterilization, endoscopes typically are rinsed with water filtered down to the 0.2 micron (200 nanometer) level. Unfortunately, many viruses, endotoxins, and prions are smaller than 200 nanometers, meaning that they can remain in the water even after filtration. Also, as reported in the articles mentioned above, water and water filters are known sources of contamination. Even more troubling, however, is the statement by one expert that "there are no independent data in the medical literature that support the production of sterile water (defined as containing fewer than 10^{-6} CFU/ml and fewer than 5 endotoxin units/ml) by passing unprocessed water (that is, un-sterilized water, such as water that flows though a hospital's tap) through a bacterial (e.g., 0.1 or 0.2 micron) filtration system" (See Comments by L. Muscarella (Custom Ultrasonics) on AAMI TIR7:1999, Chemical Sterilants and Sterilization Methods: A Guide to Selection and Use, downloaded from

the website myendosite.com). Moreover, there is no currently available system that monitors the biological content of filtered water to insure its sterility when used in conjunction with medical item cleaning or sterilization apparatuses. Finally, having to add additional sterilization steps and/or use sterilized (e.g., autoclaved) water becomes tedious and expensive.

Ozone is a well known sterilant. Ozone was first used for drinking water treatment in 1893 in the Netherlands. While being used frequently in Europe for drinking water disinfection, it was slow to transfer to the United States. Indeed, early application of ozone for water treatment in the United States was primarily for non-disinfection purposes such as color removal or taste and odor control. Today, ozone also is known to oxidize oils and reduce scale build-up. Nonetheless, the strongly oxidative qualities of ozone also present problems in that the use of ozone for the cleaning and disinfecting of items will often result in permanent damage to the item, especially if it is exposed to ozone for long periods while attempting to completely clean and decontaminate all surfaces.

Thus, while ozone applications to water and water line disinfection are now fairly common, these methods have not become widespread in other sterilization applications because they rely on a treatment system that reticulates ozonated water through the entire treatment area during repeated cleaning cycles in order to achieve and maintain disinfection. Such constant treatment is not possible for most items (and especially medical items) due to the damage that continual or repeated exposure to ozone would cause.

Even with recent advances in cleaning devices and methods, such as those invented by Langford (see, for example, U.S. Patent 5,443,801), there still remains the problem of balancing the need for complete cleaning, disinfection, and degradation of all chemical residues on an item with preventing or mitigating damage to that item and to the environment.

Therefore, there continues to be a need for a cleaning and decontaminating method that, without damaging the item being treated, helps to ensure sterility, assists in loosening difficult soiling, such as biofilm-entrained contaminants and other hydrophobic compositions or films, and degrades chemicals so that effluent is substantially free of harmful residues.

SUMMARY OF THE INVENTION

The invention generally involves a method of synergistically treating soiled items, such as medical instruments, with ozone and/or combinations of ozone with one or more cleaners or sterilants as a supplement to conventional cleaning/sterilization regimens. Ozone or ozonated fluids are not used as a primary (or sole) cleaning or sterilizing agent. Instead, ozone is used as a secondary or supplemental agent to (1) facilitate cleaning, (2) prevent re-contamination, and (3) degrade residual chemical agents, such as sterilants or detergents, from both the instrument and the wash/rinse effluent.

The general concept is that treating an item with ozone as a supplemental initial, intermediate, and/or final treatment step, in cooperation with one or more other chemicals used to clean and sterilize the item, ensures that the item and effluent are free of soiling, infectious agents, and chemical residues without causing any oxidation-related damage to the item. Moreover, given the recent focus on the need to provide an "overkill factor" to prevent re-contamination of endoscopes and medical item processing equipment, the invention provides for the ozonation of filtered (or unfiltered) rinse water commonly used in existing sterilization systems.

An added point of novelty of this invention is that supplemental ozone treatment facilitates the use of very effective yet non-preferred cleaning agents and sterilants. For example, the European Union and Australia have recommended against the use of glutaraldehyde for sterilizing endoscopes due to pollution and exposure-based heath concerns. By adding ozone treatment to the end of the glutaraldehyde sterilization process, harmful chemical residue is degraded. Moreover, the use of ozone in

combination with other chemical cleaning or sterilizing agents before, during, or after the cleaning and sterilizing process produces a synergistic effect. That is to say, adding ozone treatment to other cleaning and sterilizing treatments produces markedly improved results while minimizing oxidation damage and chemical pollution. Another benefit is that the other chemicals can be used in lesser amounts.

Accordingly, in one embodiment of the invention, a method of using ozonated fluid is provided as a "pre-rinse" to solubilize hydrophobic residue (e.g., biofilm deposits), thereby making the cleaning/sterilizing process more efficient. In other words, the invention involves a new and improved method of using ozone as a "pre-rinse" to loosen soil such that further cleaning and sterilizing would be more effective. Preferably, the item to be cleaned or sterilized is pre-rinsed by having ozonated fluid pass back-and-forth over the exterior and through any openings in the item. In another embodiment, a "final rinse" of a medical item is made with ozone to prevent re-contamination and to degrade chemical sterilant and cleaning chemical residue on the item and in the effluent, thus allowing the discharge of the same into the sewer. Still other embodiments feature co-treatments of ozone and cleaning or sterilizing agents.

Thus, it is a primary objective of the invention to provide a medical item cleaning method that improves cleanliness and ensures sterility while rendering the effluent substantially harmless.

Further, an object of the invention is to provide a cleaning method that effectively utilizes ozone while minimizing damage to the item being cleaned.

Yet another object of the invention is to provide a cleaning method that is adaptable for use in supplementing currently existing cleaning methods.

An additional object of the invention is to provide a cleaning method that is economical and inexpensive to utilize.

Still another object of the invention is to provide a cleaning and sterilizing method that may be used in conjunction with a wide variety of cleaning or sterilizing apparatuses.

Yet another object of the invention is to provide a method for ensuring the sterility of water used to rinse endoscopes or other items after cleaning and sterilization have taken place.

A further object of the invention is to provide of method of preventing re-contamination through the use of ozone of equipment that processes used medical items, assuring, for example, that any trays, ports, and chambers of such equipment are kept sterile.

In accordance with these and other objects, there is provided a new and improved ozone treatment method that utilizes supplemental pre-treatments, co-treatments, and/or final rinses with ozone or water that has been ozonated. The method is especially useful in the treatment of water entering an apparatus used to clean and/or sterilize a medical item to provide an "overkill" effect that prevents re-contamination of the item, the apparatus, and/or a water filter used therewith.

Various other purposes and advantages of the invention will become clear from its description in the specification that follows. Therefore, to the accomplishment of the objectives described above, this invention includes the features hereinafter fully described in the detailed description of the preferred embodiments, and particularly pointed out in the claims. However, such description discloses only some of the various ways in which the invention may be practiced.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention relates generally to a method of treating soiled items that combines ozone treatment with cleaning and/or sterilizing treatments involving one or more chemical agents. In other words, ozone is not used as a primary cleaning or sterilizing agent, but, rather, ozone treatment is provided only to supplement other cleaning/sterilizing agents.

Thus, the problems associated with ozone use (e.g., oxidative damage) are overcome while beneficial results are produced.

The synergistic effects produced by combining ozone with other chemical treatment regimens greatly increases cleaning and sterilizing options. For example, effective cleaning and sterilizing substances that currently are not widely used due to health and pollution concerns can now be utilized because virtually any chemical will be degraded when exposed to ozone. The synergistic benefits of providing ozone treatment with other chemical agents also extend to difficult cleaning applications. Indeed, one of the main problems with cleaning agents in use today is that they do not efficaciously remove the "greasy residue," such as cellular lipids, fat particles, or biofilm. However, despite the industry-wide reservations to ozone use (due to the damage prolonged exposure can cause to medical items), the inventor has discovered that ozone treatment in combination with existing cleaning and sterilizing methods can solve this and other problems in order to advance the methods of the art.

Accordingly, in some embodiments of the invention, ozone is used as a "pre-soak" or "pre-rinse" to help break down or loosen soil, such as proteins, lipids, or other hydrophobic biomatter. In other embodiments, combinations of ozone with cleaning agents are used to clean and degrade contaminants and chemical residue. In still other embodiments, an item is first cleaned using, for example, a detergent. Afterwards, a sterilant is applied and then removed with a rinse of ozone (e.g., ozonated water) washed over and through the endoscope in preparation for subsequent use with a patient. Still another embodiment involves treating rinse water with ozone to prevent re-contamination of the item.

Within this discussion, endoscopes will be used as an example of an item or instrument to be cleaned. However, the invention is not intended to be limited to this one type of item. Rather, the inventor contemplates use of the invention with any tubular item as well as a variety of other items such as circuit boards, medical instruments, dental instruments, and other items in which reliable cleaning and/or sterilization is required.

Ozone exists as a gas at room temperature. The gas is colorless with a pungent odor readily detectable at concentrations as low as 0.02 to 0.05 ppm (by volume), which is below concentrations of health concern. Ozone is a powerful oxidant, second only to the hydroxyl free radical, among chemicals typically used in disinfecting treatments. Therefore, it is capable of oxidizing (and thereby damaging) many organic and inorganic compounds used in medical items, such as endoscopes.

Ozone is sparingly soluble in water. At 20°C, the solubility of pure ozone is only 570 mg/L. Ozone concentrations used in water treatment are typically below 14 percent, which limits the mass transfer driving force of gaseous ozone into the water. Consequently, typical concentrations of water-soluble ozone range from <0.1 to 1mg/L, although higher concentrations can be attained under optimum conditions.

Basic chemistry research has shown that ozone decomposes spontaneously in water by a complex mechanism that involves the generation of hydroxyl free radicals. The hydroxyl free radicals are among the most reactive oxidizing agents in water, with reaction rates on the order of 1010 - 1013 M^{-1} s^{-1}, approaching the diffusion control rates for solutes such as aromatic hydrocarbons, unsaturated compounds, aliphatic alcohols, and formic acid. On the other hand, the half-life of hydroxyl free radicals is on the order of microseconds. Therefore, concentrations of hydroxyl free radicals can never reach levels above 10 –12 M.

Chemically speaking, ozone can react either by direct oxidation of compounds by molecular ozone (O_3(aq)) or by oxidation of compounds by hydroxyl free radicals produced during the decomposition of ozone. The two oxidation pathways compete for substrate (i.e., compounds to oxidize). The direct oxidation with aqueous ozone is relatively slow (compared to hydroxyl free radical oxidation) but the concentration of aqueous ozone is relatively high. On the other hand, the hydroxyl radical reaction is fast, but the concentration of hydroxyl radicals under normal ozonation conditions is relatively small.

Under acidic conditions, the direct oxidation with molecular ozone is of primary importance; and under conditions favoring hydroxyl free radical production, such as high pH, exposure to UV, or addition of hydrogen peroxide, the hydroxyl oxidation starts to dominate. The spontaneous decomposition of ozone occurs through a series of steps. The exact mechanism and reactions associated have not been established, but mechanistic models have been proposed. It is believed that hydroxyl radicals form as one of the intermediate products, and can react directly with compounds in the water. The decomposition of ozone in pure water proceeds with hydroxyl free radicals produced as an intermediate product of ozone decomposition, resulting in the net production of 1.5 mole hydroxyl free radicals per mole ozone.

Because ozone is an unstable molecule, it should be generated at the point of application. It is generally formed by combining an oxygen atom with an oxygen molecule. This reaction is endothermic and requires a considerable input of energy. Ozone can be produced several ways, although one method, corona discharge, predominates in the ozone generation industry. Ozone can also be produced by irradiating an oxygen-containing gas with ultraviolet light, electrolytic reaction and other emerging technologies. Most ozone generators currently use ultraviolet radiation. These are usually the lowest cost ozone generators on a per unit basis. This decrease in cost is due to the fact that the air does not go through an initial drying process.

Newer units being produced utilize a corona discharge technique which dry the air before charging the air with ozone. This drying permits the corona discharge apparatus to produce a higher ozone concentration. For minimal expenditures of electrical energy, ozone normally is produced from dried air (-60 degrees Fahrenheit dew point) in concentrations of one to two percent and from dry oxygen in concentrations of two to four percent. More than eighty percent of the electrical energy applied to the electric discharge field is converted to heat and, if this is not quickly removed from the cell, the heat causes rapid decomposition of the ozone back to oxygen. For additional guidance in ozone production and its uses, see U.S. Patent No. 5,207,237.

For cleaning or sterilizing methods involving the use of ozone, it is important to recognize that the time of exposure and concentration of ozone will vary based on a number of parameters, such as the quantity and size of items being treated, the volume of the cleaning or sterilizing apparatus, and the nature and amount of "soil" on and in the item. Preferably, ozonated water is used to treat items for 5-30 minutes at a concentration of 1-10% ozone by volume.

In terms of checking the progress of ozone-assisted cleaning, existing standards used for monitoring cleaning efficacy before passing from the wash/rinse cycle of a given cleaning apparatus would be chosen to meet the standards of the time or the situation. The preferred standard is set forth by the Food and Drug Administration, including flow-rate and size of particles found in Particulate Matter in Injections, commonly known as USP 788 Specification.

A number of known cleaning and sterilization methods are readily available. Some are performed in automatic endoscope reprocessors, while others are done manually. For example, Yale Medical School recommends that an endoscope can be manually cleaned by placing the distal end of the endoscope into an enzymatic detergent solution followed by applying suction to the solution through the biopsy/suction channel until the solution is visibly clean. One then alternates the suctioning of clean detergent solution with air several times, followed by removing the air under vacuum (further details are available online at Yale's Internet website info.med.yale. edu/ynhh/infection/steril/standards). To supplement this cleaning method, ozonated water (2% by volume) could be used to pre-rinse (preferably, by moving the ozonated water over and through the endoscope continuously) for 5 minutes before the washing protocol is implemented in order to loosen the soil in and on the endoscope. Alternatively, five minutes of ozonated water washing could be substituted for the final "clean detergent solution" rinse to degrade residual detergent before sterilization commences.

The following additional examples are meant to further illustrate, but not to limit, the invention.

Example 1

1. PURPOSE

The purpose of this test is to document the results of engineering characterization testing performed on a automatic endoscope reprocessor, the Langford I.C. Systems Sterilizer Cleaner (see U.S. Patent No. 5,906,802 for layout and guidance in the use of this reprocessor). This test is intended to determine that a test lumen scope is clean by visual inspection only (Example 2 describes a test to quantify the level of sterility).

2. SCOPE

This test seeks to describe methods and test results for cleaning efficacy of individual and combined cycle phases on mock devices used to simulate a colonoscope. Testing was performed on DWGX-0129-01888, Cleaner, Sterilizer Breadboard.

3. EQUIPMENT AND CALIBRATION

4.1 EQP-0129-0001,Thermocouple Omega Model HH21 Type J, K, T.

4.2 Birmingham simulated respiratory tract soils

4.3 Hucker's simulated fecal soil

4.4 SIMPLE GREEN cleaner (Sunshine Makers, Inc)

4.5 LESTOIL concentrated cleaner (The Clorox Company)

4.6. Digital camera

4.7 250 ml plastic graduated cylinder

4.8 Device under test

a. DWGX-0129-01888, Cleaner Sterilizer Apparatus Breadboard

b. DWGX-0129-01889, Mock Colonoscope Assy

5. TEST DESCRIPTION

Testing was conducted to determine initial parameter settings necessary for effective cleaning of Birmingham soil and Hucker's soil from mock scope and simulated scope lumens. The scope lumens and mock scope were inoculated with either the Birmingham soil or the Hucker's soil (at a level that is 100x the level of soiling required FDA test standards) and left sitting for a one hour time period to permit some drying. In this test,

we determined cleaning effectiveness by visual inspection only. This was done by running the Sterilizer Cleaner machine with varying baffle configurations, temperatures, cleaners (type and quantity), speed and time.

After a test was completed, the resulting pressure was recorded on the log sheet along with test results. Depending on the effectiveness of the first cycle of the test, a second clean cycle was run to show the mock lumen or mock scope was clean by visual inspection. Other times a first clean cycle was run and a second rinse (water only) cycle was run to further clean the test lumen or scope. After the test Lumen or scope was clean by visual inspection, a digital picture was taken and stored for future reference. The test lumen then was bagged and tagged and stored for future reference.

6. TEST RESULTS AND CONCLUSIONS

The Langford I.C. Systems Sterilizer Cleaner performed effectively at cleaning out both Birmingham soil and Hucker's soil from the exterior and the interior of mock lumens and the mock scope. The two cleaning agents were used and seemed to be equally effective. The Langford I.C. Systems Sterilizer Cleaner performed effectively at pressures as little as 4 psi and at temperatures as low as 110°F for washes or rinses of as little as 5 minutes in length. The preferred rate of "liquid displacement" (i.e., the back-and-forth liquid cycling rate in the item-washing chamber of the Sterilizer Cleaner) is 1 gallon per 2 seconds. Based on these results, a number of different cleaning protocols may be used successfully. One preferred protocol involves using 250 ml of SIMPLY GREEN detergent to wash the endoscope for 5 minutes at 110° F and 5 psi on the 1 gallon/2 seconds liquid-displacement setting, followed by a water rinse at the same temperature and pressure.

7. SUPPLEMENT: ADDING OZONE TREATMENT

a. Prior to the first cleaning cycle with a detergent, the mock scopes are exposed to ozonated water (4% by volume) at a liquid-displacement rate of 1 gallon/2 seconds for 5 minutes to loosen soil. The ozone is generated by corona discharge and added to water in the chamber fill line thru a Mazzei venturi injector at a rate of 1.25g/hr at 5 SCFH dry

air flow (per an 11 gallon system, but can be adjusted for other volumes). After ozone exposure, the scopes are cleaned using 250 ml of SIMPLY GREEN detergent and washing for 5 minutes at 110° F and 5 psi on the 1 gallon/2 second liquid-displacement setting, followed by a water rinse at the same temperature and pressure.

b. After the cleaning cycle is complete, the rinse water is ozonated by corona discharge as described above in step a. The mock scopes are then rinsed with the treated water for 5 minutes to degrade any residual detergent.

Example 2

The biopsy lumen of three colonoscopes were loaded with Hucker's Soil (100x more than required by FDA test standards) and inoculated with pathogens from an American Society of Test Methods kit. The scopes were left sitting for a 24 hour time period to permit some drying. Using the same Langford I.C. Systems Sterilizer Cleaner liquid-displacement settings as in Example 1, each colonoscope was subjected to one detergent wash at 4 psi for 10 min with 250 ml of SIMPLE GREEN cleaner in 10 liters of water followed by three 5 min rinses with 10 liters of filtered tap water. For the last (third) rinse, ozone generated by corona discharge was added to the water thru a Mazzei venturi injector connected to the incoming water line of the Langford reprocessor apparatus. The ozone was added to the water at a rate of 1.25g/hr at 5 SCFH dry air flow.

Tests performed to quantify the level of decontamination on the three mock scopes used in this example indicated that two of the scopes showed a log 10^{-5} pathogen kill (indicating high level disinfection) while one scope had log 10^{-6} pathogen kill (indicates sterility). Visual inspection revealed no apparent damage to any endoscope surface.

Especially given the extremely high level of soiling, these results are much better than has previously been achieved for any known cleaning/disinfecting protocol, which typically results in a log 10^{-4} pathogen kill or less. Hence, supplementing existing

endoscope reprocessing methods with ozone treatment results in a quantitative difference in decontamination without damage to the endoscope.

Example 3

In this example, a partitioned cleaning and sterilizing device of the type described and illustrated in U.S. Patent No. 5,711,921 is utilized. The endoscope is positioned to extend through the partition such that one opening of the endoscope lies in one chamber and another opening of the endoscope lies in the other chamber. The partition between the chambers need not be an absolute partition and, in this example, the partition fits loosely around the endoscope so that as the medium (i.e. a liquid detergent, sterile water, a liquid sterilant, or a sterilant gas) surges from one chamber to the other, the medium washes over the exterior of the endoscope and simultaneously sweeps through the interior of the endoscope. The device creates this "surge" through the use of one or more flexible membranes. By deforming the flexible membrane (inward and outward), a pressure or suction is created which results in a flow (liquid displacement) between the chambers to equalize the pressure between them.

250 ml of detergent is added to 10 liters of water and is used to wash the endoscope for 10 min. The scope is then rinsed twice for 5 minutes each with 10 liters of filtered tap water. After the last water rinse, 10 liters of a liquid chemical sterilant (preferably 1 ounce paracetic acid per 5 liters of water) are added to the cleaner/sterilizer and the endoscope is washed for 5 minutes. Those of ordinary skill in the art readily recognize various other sterilants which can be used in this context.

In order to degrade any sterilant residue and to provide a final "overkill" treatment to prevent re-contamination of the endoscope (and the filter, cleaning chamber, or ports of the reprocessor equipment) by the filtered water, a final rinse with 10 liters of water ozonated at 1g/hr at 5 SCFH dry air flow is performed for 5 minutes. Alternatively, the overkill treatment with ozonated water is provided by ozonated, filtered water stored in tank. The ozone is continuously added to the water in the tank by re-circulation past the

venturi. Thus, the sterility of the water is ensured without exposing the reprocessor components or items to be cleaned to a constant supply of freshly generated ozone.

It should now be readily understood that ozone or an ozonated fluid could be used prior to, concurrent with, or after the cleaning steps described in order to improve cleaning and/or breakdown the detergent. Likewise, ozone or an ozonated fluid could be applied prior to, concurrent with, or after a chemical sterilant. Preferably, at least the final rinse water used in any protocol should be ozonated at the point of application to prevent re-contamination of the cleaned and sterilized item. This is especially true if the sterilization method relies on the use of filtered tap water.

Various changes in the details and components that have been described may be made by those skilled in the art within the principles and scope of the invention herein described in the specification and defined in the appended claims. Therefore, while the present invention has been shown and described herein in what is believed to be the most practical and preferred embodiments, it is recognized that departures can be made therefrom within the scope of the invention, which is not to be limited to the details disclosed herein but is to be accorded the full scope of the claims so as to embrace any and all equivalent processes and products. All references cited in this application are hereby incorporated by reference herein.

What is claimed is:

1. A synergistic method of cleaning a soiled apparatus, comprising the steps of:

a. pre-rinsing said soiled apparatus with ozone to loosen the soil,

b. applying a cleaning agent; and

c. cleaning said soiled apparatus until the soil is removed.

2. The method of claim 1, wherein said soiled apparatus comprises an endoscope.

3. The method of claim 1, wherein ozone comprises an ozonated liquid.

4. The method of claim 3, wherein said ozonated liquid includes between 0.1 and 15 percent ozone by volume.

5. The method of claim 1, wherein said soil comprises biofilm.

6. The method of claim 1, wherein step b additionally comprises applying ozone in combination with said cleaning agent.

7. The method of claim 1, further comprising the step of rinsing a cleaned apparatus with ozone after step c is complete.

8. A method of supplementing a sterilizing process for an item harboring bio-contaminants, comprising the steps of:

a. cleaning said item in accordance with a pre-determined method,

b. applying a chemical sterilizing agent to said item in accordance with a pre-determined sterilizing method; and

c. rinsing the item with ozone to substantially degrade any remaining chemical residue and biomatter on or in said item.

9. The method of claim 8, wherein said item comprises an endoscope.

10. The method of claim 8, wherein said chemical sterilizing agents are selected from the group consisting of glutaraldehyde, paracetic acid, and ethylene oxide.

11. The method of claim 8, wherein ozone comprises an ozonated liquid.

12. The method of claim 11, wherein said ozonated liquid includes between 0.1 and 15 percent ozone by volume.

13. The method of claim 8, wherein said rinsing the item with ozone of step c is done in combination with step b such that said liquid chemical sterilizing agent is also substantially degraded.

14. A method of supplementing a cleaning and sterilizing process for a soiled item having bio-contaminants, comprising the steps of:

a. pre-rinsing said soiled item with ozone to loosen the soil,

b. applying a cleaning agent to the item,

c. cleaning said soiled item until a clean item is produced,

d. applying a chemical sterilizing agent to said clean item to achieve decontamination; and

e. rinsing the clean item with ozone to substantially degrade any remaining chemical residue and biomatter on or in said apparatus.

15. The method of claim 14, wherein said soiled item comprises an endoscope.

16. The method of claim 14, wherein ozone comprises an ozonated liquid.

17. The method of claim 16, wherein said ozonated liquid includes between 0.1 and 15 percent ozone by volume.

18. The method of claim 14, wherein said soil comprises biofilm.

19. The method of claim 14, wherein step b additionally comprises applying ozone in combination with said cleaning agent.

20. The method of claim 14, wherein said chemical sterilizing agents are selected from the group consisting of glutaraldehyde, paracetic acid, and ethylene oxide.

21. A method of preventing re-contamination of a cleaned and disinfected item, comprising:

a. rinsing said cleaned and disinfected item with water; and

b. flushing said item with ozone.

22. The method of claim 21, wherein said item is an endoscope.

23. The method of claim 21, wherein said water is filtered tap water.

24. The method of claim 21, wherein the flushing of said item with ozone is achieved by ozonating said water.

25. The method of claim 21, wherein said item is contained within a cleaning or sterilizing apparatus when step b occurs.

26. The method of claim 25, wherein ozone is added to the water prior to the water entering the cleaning or sterilizing apparatus containing said item.

27. A method of preventing cross-contamination of components within a sterilizing apparatus, comprising:

a. disinfecting an item placed within said sterilizing apparatus according to a predetermined method; and

b. flushing said components with ozone after the completion of step a.

28. The method of claim 27, wherein said components comprise a chamber, a filter, a tray, and a port.

ABSTRACT

Methods of treating soiled items, such as medical instruments, with supplemental ozone treatment, such as combinations of ozone and one or more cleaning agents or sterilants, are provided. The methods involve treating soiled items with ozone to facilitate cleaning, ensure complete sterility, and degrade residual chemical agents, such as sterilants or cleaning agents, from both the instrument and wash/rinse effluent. By treating an item with ozone in a supplemental wash or rinse in cooperation with one or more other chemicals used to clean and sterilize the item, one can ensure that the item and effluent are free of soiling, infectious agents, and chemical residues while minimizing any oxidation-related damage to the item or pollution of the environment.